- 8. Mutated PIV with altered epitope phenotype
- 9. Mutated PIV with alteration in L protein
- 10. Mutated PIV with alteration in N protein
- 11. Mutated PIV with alteration in C protein
- 12. Mutated PIV with alteration in F protein
- 13. Mutated PIV with alteration in HN protein
- 14. Mutated PIV with alteration in 3' leader sequence
- 15. Mutated PIV with alteration in N gene start sequence
- 16. PIV vector comprising sequence encoding cytokine
- 17. PIV vector comprising sequence encoding T-helper epitope
- 18. PIV vector comprising sequence encoding immunoprotective microbial

protein

- 19. Mutated PIV with restriction site marker
- 20. Mutated PIV with one or more mutations incorporated from specifically named mutant strains

## **REMARKS**

Applicants respectfully request that that the election of species requirement be reconsidered for the following reasons.

The foregoing proposed species identified by the Office are related in many aspects and in other aspects are linked through generic and specific claims that combine different elements and limitations identified by the Office as allegedly characterizing the proposed species. Election of one species from the proposed list of species, requiring identification of generic claims and listing of all claims that read on one elected species, in this context would impose an undue burden on Applicants. Moreover, the species proposed by the Office are selectively directed to "Chimeric PIV", "Mutated PIV", or "PIV vector"—and therefore do not correspond directly to subject matter encompassed by numerous pending claims directed to, e.g., isolated polynucleotides, cell or cell-free compositions, methods for producing infectious PIV, and immunogenic compositions. This lack of parity further complicates Applicants' burden for responding to the species election requirement.

As noted above, the species identified by the Office, although they may comprise separate and/or distinct inventions, are sufficiently related that no undue burden is imposed upon the Office to prosecute all pending claims on the merits in a single application. Such a finding is consistent with the Office's former withdrawal of a Restriction Requirement directed to these claims. Moreover, referring to MPEP § 808.02, it is not believed that the subject matter of these claims has "attained recognition in the art as a separate subject for inventive effort, and also a separate field of search." On this basis, it is submitted that the burdens of defining and electing a single species and segregating the claims accordingly, particularly in light of the confusing species classification presented by the Office, is believed to outweigh any burden on the Office to evaluate the claims on their merits in a single application.

In the event the Office does not withdraw the species election requirement, Applicants provisionally elect the species identified by the Office as species (3), "Mutated PIV with attenuated phenotype." However, Applicants respectfully submit that that this classification does not accord fully with the structure of the pending claims, and therefore reserve the right to amend the claims, including by presentation of additional generic claims, and/or to present further comments to clarify the scope of the elected species.

In accordance with Applicants' provisional election of species (3) it is further submitted that the Office should also examine all claims embracing or overlapping the subject matter identified by the Office as species (4)-(7). These proposed species are (4) "Mutated PIV with ts phenotype", (5) "Mutated PIV with cold-adapted phenotype", (6) "Mutated PIV with small plaque phenotype", and (7) "Mutated PIV with host range phenotype". Each of these species as set forth by the Office clearly fall within the scope of the elected species (3)—in that all of the phenotypes identified are generically known to be attenuated phenotypes. This commonality of an attenuated phenotype provides a clear functional relationship between the proposed species.

In provisionally designating generic claims and claims that read on Applicants' provisionally elected species, Applicants presume that the Office intended to co-classify the subject matter of the invention directed to isolated polynucleotides, cell or cell-free compositions, methods for producing infectious PIV, and immunogenic compositions, in accordance with the proposed species classification set forth in the election requirement, which

was simplified to only include Chimeric PIV", "Mutated PIV", or "PIV vector". The provisional claims designations set forth below are formulated accordingly.

Also for the purpose of provisionally designating generic claims and claims that read on Applicants' provisionally elected species, the accompanying Second Preliminary Amendment is enclosed as a contingent submission. If the Office declines to withdraw the imposed species election requirement, entry of the Amendment is autphorized. If the requirement is withdrawn, the Amendment shall be regarded as informal and withdrawn form the record. The purpose of this contingent Amendment is to more distinctly set forth aspects of the invention that are generic to, or overlap with, the provisionally elected species. Submission and entry of the accompanying contingent Amendment is without prejudice, and Applicants reserve the right to prosecute any subject matter of the invention withdrawn thereby.

Presuming that the accompanying contingent Amendment is entered, the following designation of generic claims and claims that read on the elected species (i.e., generally corresponding to the species identified by the Office as species 3-7, in whole or in part, is presented for the Office's consideration. Claims 11, 48-61, 91-93 and 118-120 have been designated by the Office as generic. Not all of these claims wholly embrace the designated species. For example, claim 48 is directed to a cell or cell free composition. Within the composition of claim 48, members of the elected species can alternatively fall within the designated generic claims 49 and 50 (directed to a PIV particle that is either a virus or subviral particle, respectively). Thus, Applicants presume that the designation of generic claims is neither strict nor binding, and in the interest of expediting prosecution of the application do not contest the designation at this time. However, it is proposed that claims 95 and 96, directed to a PIV particle that includes a "cDNA" genome or antigenome or is a "human PIV", are also consistent with the Office's proposed identification of generic claims. That is, these claims are "general" subject matter within the invention but do not necessarily embrace all members of the elected species to. In this regard, Applicants reserve the right to amend the claims, including by addition of generic claims, and submit further remarks to clarify what is strictly generic and specific subject matter within the invention.

Other than the proposed generic claims, the remaining claims (as contingently amended in the Second Preliminary Amendment submitted herewith) which are believed to

read on the elected species, wholly or in part, are submitted to include claims 12-47, 62-72, 76-83, 88-90, 98-99, 102-115, 117, 125-128, 130-36, and 138-143.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-467-9600.

Respectfully submitted,

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